

REMARKS

The office action dated January 24, 2006 (the "Office Action") has been received and carefully noted. Claims 13-20 were examined. Claims 13-20 were rejected. Claim 13 is amended. Claims 13-20 remain in the application.

I. Claims Rejected Under 35 U.S.C. § 103

Claims 13-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over in view of U.S. Patent No. 6015804 issued to Golub ("*Golub*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, the cited reference does not teach or suggest all of the claim limitations of independent claim 13. Claim 13 includes the limitation of: after the contacting, isolating the blood or fraction thereof having the increased cytokine receptors. On the other hand, *Golub* describes a method of enhancing endogenous interleukin-10 production in mammalian cells and tissues, which includes administering an effective amount of a tetracycline derivative. (Abstract) The isolating of the blood or fraction thereof having the increased cytokine receptors is not taught or suggested in *Golub* for at least the following reasons: (i) *Golub* describes a method for increasing cytokines whereas claim 13 describes a process for producing a composition which includes cytokine receptors, and (ii) *Golub* relates to cytokines (not cytokine receptors) whereas Claim 13 describes a process for producing a composition including cytokine receptors. In *Golub*, there is no teaching or suggestion for a process to produce a composition. Moreover, *Golub* does not teach or suggest isolating the blood or fraction thereof having the increased cytokine receptors.

In addition, there is no motivation either within *Golub* or in the knowledge generally available to one of ordinary skill in the art (at the time of the claimed invention) to modify the reference to make obvious claim 13. *Golub* is concerned with enhancing the production of the *cytokine* IL-10. (col. 5, lns. 43-44) In contrast, claim 13 is directed to a process for producing a composition, which includes a three-fold increase in *cytokine receptors* as compared to the

endogenous levels of cytokine receptors in a healthy mammal, which decreases the pathological conditions caused by an overproduction of cytokines. (see ¶ [0006]) In the Summary of the Invention, Applicant discloses “blood-derived compositions and methods of treating viral hemorrhagic diseases or disorders and other diseases involving a cytotoxic response in which . . . IL-1 . . . [is] elevated.” (¶ [0023]) In other words, Applicant discloses a technique for the uptake of excessive cytokine, while *Golub* is concerned with enhancing cytokine production. Thus, *Golub* actually teaches away from claim 13. Consequently, taking *Golub*, there would not be any reasonable expectation in success in isolating the blood or fraction thereof having the increased cytokine receptors, as disclosed in claim 13, because *Golub* actually teaches away from Applicant’s invention.

Moreover, Applicant respectfully reminds the Examiner that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. MPEP 2141.02(V). Applicant merely states this in response to the Examiner’s Response to Arguments and in no way admits that any aspect in Applicant’s claimed invention is inherent.

Accordingly, Applicant respectfully submits that the independent claim 13 and its respective dependent claims are patentably allowable in view of *Golub*.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 13-20, patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800x766.

Respectfully submitted,

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4/24/06
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